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EXAMINER

LI, QIAN JANICE

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,888

Applicant(s)

TAKEBE ET AL.

Examiner

Q. Janice Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-16 are pending in the application. Claims 4, 7, 10 have been amended.
Claims 1-16 are under current examination.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §119(e) & §120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Appropriate correction is required.

Claim Objections

Claim 9 is objected to because of the following informalities: "ftlrther" in line 4 should be "further". Appropriate correction is required.

Claim 11 is objected to because of the following informalities: "mzd" in line 3 should be "and". Appropriate correction is required.

Claim 14 is objected to because of the following informalities: "perfonnance" should be "performance". Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6 and 9-12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the materials comprising isoflavone aglycone exist in nature, such as fermented grains, therefore, the claims are drawn to a product of nature. Amending claims to recite "isolated" would obviate this rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The factors to be considered when determining whether the disclosure satisfies the enablement requirements and whether undue experimentation would be required to make and use the claimed invention are summarized in *In re Wands*, (858 F2d 731, 737, 8 USPQ 2d 1400, 1404, (Fed Cir.1988)). These factors include but are not limited to the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability of the art, the breadth of the claims, and amount of direction provided. The factors most relevant to this rejection are the scope of the claims relative to the state of the art and the levels of the skilled in the art, and whether sufficient amount of direction or guidance are provided in the specification to enable one of skill in the art to practice the claimed invention.

Claim 1 recites "a stem cell-augmenting material", claim 2 further clarifies that stem cell encompasses embryonic and somatic stem cells such as nerve stem cells, claim 8 recites "the material having sexual performance-improving activity". These claims clearly state the nature and the intended use of the composition. With respect to claim breadth, the standard under 35 U.S.C. §112, first paragraph, entails the determination of what the claims recite and what the claims mean as a whole. "WHEN A COMPOUND OR COMPOSITION CLAIM IS LIMITED BY A PARTICULAR USE, ENABLEMENT OF THAT CLAIM SHOULD BE EVALUATED BASED ON THAT USE". (MPEP 2164.01c) When analyzing the enabled scope of the claims, the intended use is to be taken into account because the claims are to be given their broadest reasonable interpretation that is consistent with the specification. As such, the instantly disclosed material is defined as a composition for therapeutic use, i.e. to augment stem cells in certain way, whether it is the size, or

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proliferation potential, or other characteristics; and to improve sexual performance in a subject, therefore, will be evaluated by that standard.

In view of the guidance provided, the specification teaches exposing rats to radiation followed by bone marrow transplantation (BMT), and then feeding different groups of rats with regular food or food containing isoflavone aglycone. The specification teaches that rats with added isoflavone aglycone, particularly higher doses, would have higher numbers of spleen colonies post-BMT (figures 4, 7, 10, 14). However, the specification fails to teach whether the slightly increased spleen cell colonies are the results of direct effect of isoflavone aglycone on stem cells, and it fails to show any direct effect on the characteristics of any type of the stem cell itself, particularly considering that totipotent, pluripotent stem cells (embryonic), and nerve stem cells have very different characteristics compared to adult bone marrow stem cells.

In view of the state of the art and the knowledge of the skilled in the art, it is known that isoflavone aglycones have health-promoting effect in general such as taught by Kelly et al (US 6,642,212), and Takebe et al (US 6045819 and 6303161). However, it is unknown and the specification fails to teach whether the increased spleen cell colonies are the direct effect on stem cells, or indirect effects on other *in vivo* factors such as cytokines, cell growth factors, or resulting from promoting general health conditions. Accordingly, the specification fails to provide an enabling disclosure for what is now claimed.

With respect to improving sexual performance, the specification is silent regarding the mode of operation and the effect on any subject, thus, fails to provide an enabling disclosure for what is now claimed.

Therefore, in view of the limited guidance, the lack of predictability of the art and the breadth of the claims, one skill in the art could not practice the invention without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims are vague and indefinite because of the claim recitation, "stem cell-augmenting" material. The specification fails to define the phrase, which encompassing augmenting in cell size, number, renewal potential, or other traits of a stem cell. It is unclear in what aspect the material is augmenting a stem cell, thus, the metes and bounds of the claims are unclear.

Claims 8, 14 and 15 recite the limitation "having sexual performance-improving". There is insufficient antecedent basis for this limitation in the claim.

Claim 9 is vague and indefinite because the claim recitation, "said stem cell augmenting material is a product of promoting proliferation of lactic acid bacteria contained in said product". In light of the teaching of the specification and other claims,

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applicants intend to claim a material comprising isoflavone aglycone, which augments stem cells. However, this claim does not require the presence of isoflavone aglycone, and the specification fails to teach other product that augment stem cells other than isoflavone aglycone. Further, the specification fails to teach that isoflavone aglycone contains lactic acid bacteria and also promotes the proliferation of lactic acid bacteria. It is unclear what applicant intend to claim in the context of the claim and the specification, thus, the metes and bounds of the claim are uncertain.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(f) he did not himself invent the subject matter sought to be patented.

Claims 1-6 and 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by *Luksas et al* (USP 3,878,302).

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Lukas et al teach materials comprising grains fermented with Koji mold culture (e.g. column 1, lines 33-36), which would contain isoflavone aglycone. Thus, *Lukas et al* anticipate instant claims.

Please note in this and following rejections intended use limitations bear little weight on the determination of novelty of the invention. In this case, the limitation “stem cell-augmenting material” or “the material having sexual performance-improving activity” does not carry patentable weight in the determination of anticipation for the claimed products. This is because a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Please also note with regard to those product-by-process claims presented that patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it which is recited in the claims. *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985).

Claims 1-6 and 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by *Groben et al* (USP 4,214,008).

Groben et al teach a material comprising fermentate of lactic acid producing bacteria (e.g. claim 1), which would contain isoflavone aglycone. Thus, *Groben et al* anticipate instant claims.

Claims 1-6 and 9-12 are rejected under 35 U.S.C. 102(e) as being anticipated by *Bojrab et al* (USP 6,641,808).

Bojrab et al teach a material comprising fermented mixture of lactic acid producing bacteria (e.g. claim 1) and carbohydrate that promotes proliferation of lactic

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acid-producing bacteria, which would contain isoflavone aglycone. Thus, *Bojrab et al* anticipate instant claims.

Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by *Takebe et al* (USP 5,885,632).

Takebe et al teach a material comprising isoflavone aglycone (abstract), wherein the aqueous extract is further concentrated by hydrolysis (claims 7-10), wherein said isoflavone aglycone is comprised of 70-100% daizein (table 3). Thus, *Tabete et al* anticipate instant claims.

Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by *Takebe et al* (USP 6,045,819).

Takebe et al teach a material comprising isoflavone aglycone (claim 7), wherein the aqueous extract is further concentrated by hydrolysis (claim 1), wherein said isoflavone aglycone is comprised of >70% daizein (table 5). Thus, *Tabete et al* anticipate instant claims.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claims 1-16 are rejected under 35 U.S.C. 102(e) as being anticipated by *Takebe et al* (USP 6,303,161).

Takebe et al teach a material comprising isoflavone aglycone (table 4), wherein the aqueous extract is further concentrated by hydrolysis (claim 1), wherein said

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isoflavone aglycone is comprised of >70% daizein (tables 4, 5). Thus, *Tabete et al* anticipate instant claims.

Claims 1-7, 9-13, 15 are rejected under 35 U.S.C. 102(e) as being anticipated by *Obata et al* (USP 6,444,239).

Obata et al teach a material comprising isoflavone aglycone (e.g. claim 1), wherein the material produced by hydrolysis of isoflavone aglycone is further concentrated (example 3), which was made up of 40% of daizein. Thus, *Obata et al* anticipate instant claims.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claims 1-16 are rejected under 35 U.S.C. 102(e) as being anticipated by *Kelly et al* (USP 6,642,212).

Kelly et al teach a material comprising isoflavone aglycone (abstract), wherein the aqueous extract is further concentrated (column 12, line 57), wherein said isoflavone aglycone is comprised of 95% daizein (genistein:daizein=1:19, claim 13). Thus, *Kelly et al* anticipate instant claims.

Claims 1-7, 9-13, 15 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 09/284,935 which has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if published

under 35 U.S.C. 122(b) or patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future publication or patenting of the copending application.

Claims of the cited co-pending application are drawn to a material comprising grains and koji mold fermentation mixture, and the specification teaches the mixture contain isoflavone aglycone (e.g. paragraph 31), which comprising high amount of daizein. Accordingly, the claims of the cited co-pending application encompassing and anticipating the instant claims.

This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

Claims 1-16 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. Each of the above cited patents (5,885,632; 6,045,819; and 6,303,161) and the co-pending application have a different inventive entity compared to the instant application, but they anticipate instant claims, thus it is unclear who is the real inventor.

Double Patenting

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-10 of U.S. Patent No. 5,885,632. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims of the cited patent encompass the instant claims.

The claims of the present application and the cited patent are each drawn to a material comprising the fermentation product of a pulse crop and koji preparation. The claims of the present application and the cited patent differ in that the claims of the cited patent do not recited isoflavone aglycone, wherein said isoflavone aglycone is comprised of 70-100% daizein, however, the subject matter has been taught in the specification (e.g. table 3). Therefore, the inventions as claimed are co-extensive.

Claims 1-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7 and 8 of U.S. Patent No.

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6,045,819. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims of the cited patent encompass the instant claims.

The claims of the present application and the cited patent are each drawn to a material comprising the isoflavone aglycone derived from fermentate of koji preparation. The claims of the present application and the cited patent differ in that the claims of the cited patent recite other derivatives in addition to isoflavone aglycone, and do not recite that said isoflavone aglycone is comprised of 70-100% daizein, however, the subject matter has been taught in the specification (e.g. table 5). Therefore, the inventions as claimed are co-extensive.

Claims 1-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,303,161. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims of the cited patent encompass the instant claims.

The claims of the present application and the cited patent are each drawn to a material comprising the fermentation product of a pulse crop and koji preparation. The claims of the present application and the cited patent differ in that the claims of the cited patent do not recited isoflavone aglycone, wherein said isoflavone aglycone is comprised of 70-100% daizein, however, the subject matter has been taught in the specification (e.g. tables 4, 5). Therefore, the inventions as claimed are co-extensive.

Claims 1-7, 9-13, 15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent Application No. 09/284,935. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims of the cited patent encompass the instant claims.

The claims of the present application and the cited patent are each drawn to a material comprising the fermentation product of grains and koji preparation. The claims of the present application and the cited patent differ in that the claims of the cited patent application do not recited isoflavone aglycone, however, the subject matter has been taught in the specification (e.g. paragraph 31). Therefore, the inventions as claimed are co-extensive.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Amy Nelson** can be reached on 571-272-0804. The fax numbers for the organization where this application or proceeding is assigned are **703-872-9306**.

Any inquiry of formal matters can be directed to the patent analyst, **Dianiece Jacobs**, whose telephone number is (571) 272-0532.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is **703-308-0196**.

JANICE LI
PATENT EXAMINER


Q. Janice Li
Patent Examiner
Art Unit 1632



February 9, 2004